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Chairman's Foreword

It is my pleasure to introduce this sixth report on the Confidential Enquiry into Stillbirths and Deaths in Infancy in Northern Ireland.

The Enquiry has proved to be not only a unique source of local perinatal epidemiological information but has played an important role in encouraging and supporting a wide range of local initiatives which aim to improve the quality of care for mothers and their infants.

Perinatal and infant mortality rates have dropped considerably over previous decades but in Northern Ireland, as in other parts of the United Kingdom, have now levelled off around historically low levels. Much remains to be learned if we are to see them lowered further.

Modern neonatal care has accomplished enormous improvements in the survival of those babies born "too small, too soon into this breathing world" but the reason why they present so soon often eludes explanation. Many stillborn infants succumb without apparent cause. Uncovering reasons for such distressing outcome presents a challenge to all those involved in fetal medicine.

The sudden unexpected death of an infant is much less common than in earlier years but there is scope for further reduction. I am hopeful that new measures to strengthen advice to parents about infant sleeping arrangements combined with a new protocol for assembling a broad range of information will help prevent or explain many of these tragic events.

Perinatal pathology makes an enormous contribution to our understanding. I anticipate that measures to resolve the recent difficulties which have been experienced will ensure that the service is fully available and that the confidence of both professionals and parents is restored.

This is the last report under the acronym CESDI. April 2003 sees the establishment of the combination of maternal, infant and childhood deaths under the new Confidential Enquiry into Maternal and Child Health (CEMACH). Northern Ireland will participate fully in this alongside other regions as it did in CESDI.

The success of CESDI has been due to the support and involvement of professionals from throughout the province. I thank them for their interest and for their response to many of the recommendations which emerged from previous CESDI reports.

I am confident that the ongoing quest to improve outcomes under CEMACH will engage their continued support.



DR HENRIETTA CAMPBELL

Chief Medical Officer (NI)

Chairman of Northern Ireland Regional Confidential Enquiry Group

Acknowledgements

The CESDI programme has from its foundation depended on the good will, hard work and commitment of a wide range of staff in professional and administrative posts in Trusts and Boards throughout the province.

Their part in completing Rapid Report Forms, facilitating the receipt of clinical notes in preparation for enquiry panels, supporting the CESDI Diabetes Study and generally being unfailingly helpful in response to my requests or queries, has been greatly appreciated.

A particular thank you to those professionals from the pool of assessors who have given their time and energy to the serious and sensitive issues involved in confidential assessment of individual cases.

I am guided and supported to an enormous extent by my Research Associate Mrs Terry Falconer and my Secretary Mrs Christine Murnin. Their enthusiasm and competence are invaluable in keeping CESDI organised.

The key task of checking and entering the data from Rapid Report Forms is most ably carried out by Mrs Heather Blythe. Ms Joanne Fox, Midwife, has been of enormous help with the introduction of the CESDI Diabetes Study.

I welcome this opportunity to record my sincere thanks to all who have been involved.

A handwritten signature in black ink, appearing to read 'Maureen Scott', written in a cursive style.

MAUREEN SCOTT

1. Introduction

The Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) is a national enquiry, commenced on 1st January 1993 which aims to improve understanding of the ways in which risks of death in late fetal life and infancy might be reduced.

CESDI in Northern Ireland is overseen by a Regional Confidential Enquiry Group chaired by the Chief Medical Officer. Data collection and analysis are organised by a Regional Co-ordinator and Research Associate who maintain close links with an Area Co-ordinator in each Health and Social Services Board and with professionals in the hospitals and communities where the deaths occur.

There are two elements to CESDI.

1. A **survey of all deaths** from a gestational age of 20 weeks to one year after birth, whether born dead or alive.
2. A **confidential enquiry** into a sub-group of these deaths.

The confidential enquiry involves the examination of anonymised clinical records by a multidisciplinary group of independent assessors. Participants in assessment panels are drawn from Obstetrics, Midwifery, Paediatric Pathology, Paediatrics/Neonatology, General Practice and Neonatal Nursing.

The particular sub groups which have been the subject of the national CESDI enquiry since 1993 are as shown in table 1.1a.

Table 1.1a The National Work Programmes of CESDI

	Year of Study	Findings Reported
Enquiry Topic		
Intrapartum related deaths > 2.5 kg	1993	2 nd Annual Report
Intrapartum related deaths > 1.5 kg	1994-1995	4 th Annual Report
'Explained' Sudden Unexpected Deaths in Infancy	1993-1996	5 th Annual Report
1 in 10 sample of all deaths > 1kg	1996-1997	6 th Annual Report
All deaths 4 kg and over	1997	6 th Annual Report
Case Control Studies		
Sudden Unexpected Deaths in Infancy	1993-1994	3 rd Annual Report
Sudden Unexpected Deaths in Infancy	1993-1996	The CESDI SUDI studies
Antepartum Term Stillbirths	1995	5 th Annual Report
Project 27-28	1998-2000	To be reported
The Diabetic Pregnancy	2002-2003	To be reported

In addition, a range of other topics became the subject of special study as a result of observations made in the course of the enquiries (Table 1.1b).

Table 1.1.b Special Study Topics

Focus Group		
Shoulder dystocia	1994-1995	5 th Annual Report
Ruptured uterus	1994-1995	5 th Annual Report
Planned home delivery	1994-1995	5 th Annual Report
Anaesthetic complications and delays	1994-1995	7 th Annual Report
Breech presentation at onset of labour	1994-1995	7 th Annual Report
Stillbirth	1996-1997	8 th Annual Report
Audits		
Post-mortem reporting	1993	2 nd Annual Report
Post-mortem reporting	1994-1995	6 th Annual Report
CTG education	1999	7 th Annual Report
European Comparisons of Perinatal Care	1995-1998	8 th Annual Report
Use of Intrapartum Electronic Fetal Monitoring	1999	8 th Annual Report

This report, the **sixth** in a Northern Ireland series will present a range of epidemiological data on deaths reported to CESDI(NI) for the year 2001 along with some provisional figures for 2002 and an account of trends in mortality patterns since 1993.

At the commencement of Project 27/28 a national decision was taken to ‘pool’ the cases/controls and allocate them to regions so that panels did not assess cases from within their own region. While the NI CESDI Regional Confidential Enquiry Group supported this they wished that NI cases would continue also to be assessed locally. This would provide an opportunity to compare judgements made by different panels.

Cases and controls for the national confidential enquiry programme Project 27/28 were collected by all regions up to 31st August 2000 and final assessments were to be completed by 31st March 2001.

Local panels completed the assessment of NI cases and their findings and recommendations have been reported in the CESDI(NI) 1999/2000 Report¹. It was hoped that results from all Project 27/28 enquiries throughout the CESDI regions, including access to the reports on NI cases which were assessed by other regions would have been available to the Regional Co-ordinator by now to lend perspective to the local findings. However, the delays resulting from the major administrative changes affecting CESDI (see below) have meant that these will not now be available before publication of the 9th National CESDI Report in March 2003.

Progress on the current Diabetic Pregnancy programme will be reported.

A number of other issues related to, or affecting, CESDI will be discussed and some suggestions for the future place of the confidential enquiry within NI risk assessment and quality assurance/risk management programmes will be presented for consideration.

2. Return of Rapid Report Forms (RRFs)

Most units continued to notify us promptly and return RRFs (Appendix 1) which were fully and clearly completed.

Sincere thanks to all who have been such willing respondents.

We first learned of over 90% of CESDI deaths via the RRF returned by the unit where the death occurred.

Disappointingly there were some 25 deaths where our first intimation of the occurrence was on receipt of a copy of the registration of the event. These are received by us some months after the event. Apart from the time and effort required to obtain information after a long interval we cannot close the year's database and guarantee the validity of our figures until we are confident that all relevant cases have been included.

Failure to return a RRF was most often noted when death occurred other than at the place of birth.

This may have been because staff felt that by initiating the RRF they were expected to find all the information which it requires. Clearly if an infant dies at a unit other than the unit of birth the antepartum and intrapartum questions cannot be answered there. In these cases CESDI office will follow-up the missing information and this is most easily and reliably done when time intervals are short.

The early notification of a CESDI death is the key step in obtaining good information so **PLEASE SEND THE RRF AS SOON AS POSSIBLE** after the event. Do not delay the return to pursue information not readily available at the time of death.

In 2001 the total number of deaths reported to CESDI rose by some 8% from 2000 but remains lower than in any other previous year. The rise reflects an increase in stillbirths and post neonatal deaths (Table 2.1).

Table 2.1 Categories of CESDI Deaths 1993-2001

Category of Death	Year									
	1993	1994	1995	1996	1997	1998	1999	2000	2001	(2002)
Late Fetal Loss	59	45	59	69	36	58	59	54	47	53
Stillbirth	128	154	143	156	132	132	132	93	112	120
Early Neonatal Death	103	87	102	79	85	76	99	70	72	69
Late Neonatal Death	32	22	27	14	22	18	14	20	19	10
Post Neonatal Death	45	49	43	39	35	36	34	27	36	24
*TOTAL DEATHS	367	357	374	357	310	320	338	264	286	276

* The total deaths include cases where a pregnancy was terminated after the 20th week following antenatal diagnosis of severe congenital abnormality. In 2001 there were 12 such cases. Nine were categorised as late fetal loss, 2 as stillbirths and 1 infant, with large encephalocele, died shortly after delivery at 23 weeks.

() provisional total at 21.1.03

Patterns of mortality rates (Table 2.2) give perspective to these figures but readers are reminded that as total figures fall the year on year variation may be quite marked. Caution should be exercised when interpreting annual percentages and rates.

Table 2.2 Mortality Rates 1993-2001

Category of Death	Year								
	1993	1994	1995	1996	1997	1998	1999	2000	2001
Stillbirth*	5.1	6.3	6.0	6.3	5.5	5.5	5.7	4.3	5.0
Early Neonatal	4.1	3.6	4.3	3.2	3.5	3.2	4.3	3.2	3.3
Perinatal*	9.2	9.9	10.3	9.5	9.0	8.7	10.0	7.5	8.3
Late Neonatal	1.3	0.9	1.1	0.6	0.9	0.8	0.6	0.9	0.9
Neonatal	5.4	4.5	5.4	3.8	4.4	4.0	4.9	4.1	4.2
Post Neonatal	1.8	2.0	1.8	1.6	1.5	1.5	1.5	1.2	1.6
Infant	7.2	6.5	7.2	5.4	5.9	5.5	6.4	5.3	5.8

* Per 1000 live and stillbirths. Other categories are per 1000 live births.

In 2001 the stillbirth rate stood substantially unchanged from 1993 when CESDI began. Neonatal and Infant mortality were some 20% lower than when first recorded by CESDI.

Northern Ireland figures are slightly higher than those for England and Wales. Rates for all 14 CESDI regions in England are not yet available for comparison but two regions have recently published figures for 2001 which show rates higher and lower than those for NI (Table (2.3)).

Table 2.3 Perinatal and Infant Mortality 2001

Region	Perinatal Mortality	Infant Mortality
N IRELAND	8.3	5.8
REGION A	8.4	6.3
REGION B	7.0	5.1
WALES	7.6	5.6
ENGLAND	8.0	5.4

Such comparisons are however of limited value without some understanding of the birth populations to which they refer.

Survival chances largely depend on being normally formed, born at a well-advanced stage of the pregnancy and being of good birthweight.

For infants live born in NI some measures of the mortality risks associated with different birthweights and gestational ages can be estimated.

A. Birthweight

For infants born very prematurely ie weighing less than 1000g mortality is high, being over 50%. This includes some infants of extremely low birthweight ie below 750g, where mortality is around 90%. At very low birthweight mortality is little affected by whether or not the infant was normally formed but where birthweights of 2500g or greater are achieved the first year survival chances of a normally formed infant exceed 99.9% (Table 2.4).

Table 2.4 Infant Mortality Rate by Birthweight 1997–2001
(A) All Births and (B) Non Malformed Births

Birthweight in grams		1997	1998	1999	2000	2001
< 1000g	A	518.1	504.6	527.3	552.1	606.7
	B	445.8	404.2	452.6	489.6	539.3
1000 -	A	111.1	107.4	100.7	64.1	104.2
	B	78.4	60.4	60.1	45.8	51.5
1500 -	A	36.0	20.6	45.7	32.3	16.7
	B	14.4	10.3	15.7	21.7	6.7
2000 -	A	19.9	10.7	14.7	11.5	16.7
	B	5.6	2.4	2.3	5.1	2.6
2500 -	A	4.7	5.6	7.0	3.2	4.4
	B	1.3	1.6	3.5	1.8	2.7
3000 -	A	1.7	1.8	1.5	2.1	1.7
	B	0.7	0.7	0.6	1.0	0.8
3500 -	A	0.4	1.3	1.0	0.7	1.4
	B	0.4	1.2	0.8	0.5	0.8
4000 -	A	1.2	0.6	1.9	2.2	1.3
	B	1.2	0.6	1.2	1.3	0.7
All Weights	A	5.9	5.6	6.4	5.2	5.8
	B	3.9	3.9	3.6	3.9	3.7
All Weights Above 2500g	A	1.6	1.8	2.2	1.8	1.9
	B	0.7	0.9	1.2	1.0	1.1

B. Gestation

For the infant liveborn at 24-26 weeks gestation survival chance is of the order of 50%, rising to over 99% for those born at term (Table 2.5).

Table 2.5 Infant Mortality Rates by Gestational Age 1999-2001

Gestation in Weeks	1999	2000	2001
< 24	All Died	888.8	All Died
24-26	491.5	520.8	454.5
27-29	106.4	144.3	152.9
30-32	42.9	45.2	78.1
33-36	15.1	9.1	5.0
37-39	3.0	2.3	3.3
40 -	2.0	1.3	1.6
All Gestational Ages \geq 37 weeks	2.5	1.7	2.4
All Gestational Ages	6.4	5.4	5.8

Other factors which will influence comparison of NI mortality rates with those from elsewhere include the operation within the various regions of England and Wales of the Abortion Act (1967) and the differing availability, uptake and response to ante natal screening services in regions.

Each of these services will remove before 20 weeks a number of infants who in the absence of such intervention could be expected to contribute to CESDI mortality figures. The effect of such removal cannot be quantified without more detailed figures than are currently available.

In NI 19 late fetal losses, 17 stillbirths and 48 infant deaths, some 29.7% of all CESDI deaths, were recorded as being due to congenital malformation. This compares with figures of 20-25% reported from other CESDI regions (personal communication).

Trends and comparisons are also affected by subjective factors. Variations in recognition of the potential to benefit from neonatal intensive care or in the rigour with which the definitions of live and stillbirth are applied to infants born at the margins of viability may make the recording of events more likely in some regions than in others.

C. Causes of Death

The small rise in infant mortality rate seen in 2001 is largely attributable to an increased number of deaths from congenital malformation. There were 48 infant deaths from this cause in 2001 compared with 29 in 2000 (Table 2.6).

**Table 2.6 Causes of Death in Liveborn Infants 2000/2001
Wigglesworth Classification**

Cause of Death	Early Neonatal	Late Neonatal	Post Neonatal	Total
Congenital Defect				
2000	19	4	6	29
2001	27	6	16	48
Intrapartum Causes				
2000	6	0	0	6
2001	5	1	0	6
Immaturity				
2000	34	7	5	46
2001	34	7	4	45
Infection				
2000	4	4	4	12
2001	1	1	5	7
Other Specific Causes				
2000	7	0	3	10
2001	5	2	2	9
Accident/Non IP Trauma				
2000	0	0	0	0
2001	0	0	1	1
Sudden Infant Death				
2000	0	4	8	12
2001	0	2	8	10
TOTAL				
2000	70	20	27	117
2001	72	19	36	127

The detail which respondents furnished on the RRF regarding the number and nature of malformations present in infants who died was extremely limited in many cases. Since only 15 (31%) of the affected infants came to post mortem it is not possible to clarify the contribution of particular malformations to mortality.

In any case in the absence of good denominator information from a population malformation register it is impossible to know whether a rise in deaths reflects a true rising incidence, rising birth prevalence, poorer survival, a change in reporting habits, or a mixture of these.

It is a matter of some urgency that we develop an information system which will allow us to know **what** is happening. Without it we will never be able to address **why** things are happening.

Deaths from prematurity continue to account for over one third of infant deaths but if we consider the obstetric classification of these deaths, there was no discernible explanation within the mother or the infant to account for the early onset of labour and delivery, in almost three quarters of these pregnancies (Table 2.7).

Table 2.7 Obstetric Classification of Deaths from Prematurity 1999-2001

	1999 (47) %	2000 (46) %	2001 (45) %
Pre-Eclampsia	8.5	6.5	2.2
Antepartum Haemorrhage	21.3	30.4	15.6
Mechanical	2.1	2.2	0.0
Maternal Disorder	6.4	6.5	8.9
Unexplained by any maternal condition/complication	61.7	54.4	73.3
Total	100.0	100.0	100.0

() Total liveborn infants dying from Prematurity

D. Stillbirths

Stillbirth remains the largest category of CESDI deaths accounting for 112 or 39% of the total.

While the stillbirth rate in 2001 was the second lowest yet recorded it is disappointing that the record of 4.3 in 2000 was not matched.

Some 79 of the stillborn infants (70.5%) were noted to have died in utero at some stage before the mother presented at hospital and 14 (10.6%) to have died following admission. For 19 stillbirths (14.4%) respondents did not answer this question.

Maceration of some degree was noted for 42% of stillbirths. In 10 cases the death in utero was recorded as having occurred during labour, the infant being malformed in 5 cases and 5 being ascribed to intrapartum asphyxia. One of this latter group occurred following Abruption of the Placenta, one during an assisted breech delivery and three, with no apparent acute insult, died during labours at 24, 39 and 42 weeks.

Among pregnancies which came to delivery at 24-26 weeks in 2001 some 1 in 4 resulted in a stillborn infant. At term this occurs in 1-2 per 1000 deliveries (Table 2.8).

Table 2.8 Stillbirth Rates* by Gestation 1999-2001

Gestation in Weeks	1999	2000	2001
24 – 26	243.6	283.6	258.6
27 – 29	129.6	108.1	209.1
30 – 32	82.9	57.9	54.5
33 – 36	23.4	14.0	19.4
37 – 39	3.7	2.6	2.7
40 -	1.2	0.8	1.2
All Gestations	5.7	4.3	5.0

* Rate is per 1,000 total births of similar gestation.

While the number of stillbirths rose from 93 in 2000 to 112 in 2001 there was no noted rise in the proportion of deaths attributable to any specific cause. In particular the rise in congenital malformation among infant deaths was not seen in stillbirths (Table 2.9).

Table 2.9 Percentage of Stillbirths by Obstetric Classification of Cause 1999-2001

Cause of Death	1999 (132)	2000 (93)	2001 (112)
Congenital Anomaly	14.4	16.1	15.2
Isoimmunisation	0.0	0.0	0.9
Pre Eclampsia	5.3	1.1	2.7
Antepartum Haemorrhage	18.2	14.0	10.7
Mechanical	3.8	6.5	4.5
Maternal Disorder	4.6	7.5	5.4
Miscellaneous	3.8	1.1	3.6
Unexplained			
< 2.5kg	28.7	29.1	33.9
≥ 2.5kg	21.2	24.7	23.2

() = Total number of deaths on which percentages are based.

We must promote and support initiatives which seek to uncover the reasons for these unheralded deaths.

A first step towards furthering our understanding may be to reconsider the classification systems used in CESDI (Appendix 2). Any system which throws up a high proportion of ‘unexplained’ cases is failing in its purpose, to help in the quest to understand perinatal mortality and highlight areas in need of attention. Studies using other classification systems which include a category of Small for Gestational Age (SGA) or Fetal Growth Restriction (FGR) leave many fewer ‘unexplained’ and highlight the importance of growth retardation as an important component of stillbirth statistics, often occurring in mothers with no obstetric risk².

The majority of growth restriction is currently not detected. Analysis of the CESDI '1 in 10' stillbirth enquiries highlighted the fact that in many cases growth screening and assessment were considered inadequate³.

However, although there is no in-utero treatment, improvements in maternal-fetal medicine offer opportunities for recognition of risk. With appropriate surveillance and determination of the best time for delivery from an unfavourable intra uterine environment a number of these deaths might be avoided.

E. Multiple Pregnancy

There were 261 CESDI deaths as the outcome from singleton pregnancies and 25 resulted from multiple pregnancy. Two sets of triplets died, all early neonatal deaths following delivery at 23 and 24 weeks (Table 2.10).

Table 2.10 CESDI Deaths in Multiple Pregnancies 2000/2001

Category of Death	2000		2001	
	Twin Pregnancy	Triplet Pregnancy	Twin Pregnancy	Triplet Pregnancy
Late Fetal Loss	9	3	1	0
Stillbirth	2	0	5	0
Early Neonatal Death	10	0	8	6
Late Neonatal Death	2	0	2	0
Post Neonatal Death	2	0	3	0
Total	25	3	19	6

Mortality among twins remains substantially higher than for singleton pregnancies (Table 2.11).

Table 2.11 Perinatal And Infant Mortality Rates In Singleton And Twin Births 2000/2001

	2000		2001	
	Singleton	Twin	Singleton	Twin
Perinatal Mortality	7.1	18.2	7.7	19.2
Infant Mortality	4.9	21.3	5.1	19.3

Among the 19 deaths from twin pregnancy there were 5 sets of twins, 3 first born twins and six second born twins.

One first born twin who died from pneumonia and renal failure in 2001 was the sibling of an infant noted as a late fetal loss in the year 2000 following delivery at 23 weeks.

Two other first born and six second born twins had been born and died in 2001.

The gestational ages and causes of death reported for twins are as shown in (Table 2.12).

Table 2.12 Gestation and Cause of Death in Twin Pregnancy 2001

a. ***Both Twins Died***

Category of Death		Gestation	Cause of Death
TWIN 1	ENND	21	Intra Partum Asphyxia
TWIN 2	LFL	21	"
TWIN 1	ENND	22	Prematurity
TWIN 2	ENND	22	"
TWIN 1	ENND	24	Prematurity
TWIN 2	ENND	24	"
TWIN 1	ENND	25	Intra Partum Asphyxia. Donor to
TWIN 2	SB	25	acardiac-twin
TWIN 1	ENND	28	T-T Transfusion. Cardiomyopathy
TWIN 2	ENND	28	Intra Ventricular Haemorrhage and Prematurity

b. ***First Born Twin Died***

Category of Death	Gestation	Cause of Death
PNND*	23	Pneumonia. Renal Failure. Prematurity
PNND	26	Sepsis. Prematurity
PNND	37	Craniofacial Dysostosis

* This infant died at 8 months of age. Twin 2 was a Late Fetal Loss in 2000.

c. ***Second Born Twin Died***

Category of Death	Gestation	Cause of Death
SB	27	T-T Transfusion
LNND	27	Prematurity
LNND	32	T-T Transfusion
SB	32	Selective Fetocide. Trisomy 21
SB	34	Chromosomal Defect
*SB	39	Fetus Papyraceous

* Readers are reminded that gestational age refers to age at delivery. This delivery would therefore be categorised as stillbirth even though it is recognised that death in utero had been at a much earlier stage of pregnancy.

Apart from a second born twin who died in the late neonatal period as a sequela of twin-twin transfusion there were no deaths from causes other than malformation among twins liveborn after 28 weeks gestation.

3. Pathology and CESDI

Procedures for certifying death and conducting post mortem examination have recently been the subject of considerable public and professional concern and the role and practice of doctors and coroners in these procedures have been, and are being, reviewed^{4,5}.

While these reviews recognised that professionals felt committed to giving a professional and compassionate service, they were often working with obsolete or neglected guidelines and inadequate legal structures. Major changes were considered necessary.

Recommendations have been made which aim to improve public understanding of the work of pathologists, to restore public confidence and to strengthen the important contribution which accurate cause of death information makes to understanding disease in individuals and populations.

Paediatric pathology services have been particularly affected by events and the delivery of present and future services is in crisis⁶.

The CESDI aims of a 75% post mortem rate and a service provided by specialist staff working closely with clinical colleagues and parents seem less likely to be achieved than when CESDI began in 1993. If the specialty is to survive the national recruitment crises and provide appropriate training, experience and governance to those in the services, rapid and co-ordinated action by Government, Royal Colleges, Health Boards and Trusts is required.

The percentage of CESDI deaths coming to post mortem in 2001 fell below 40%. Some 95 deaths (33.2%) had a hospital post mortem and a further 17 (5.9%) were the subject of a coroners post mortem (Table 3.1).

Table 3.1 Post Mortems 1993-2001 All CESDI Deaths in N Ireland

Year	Percentage having Hospital Post Mortem	Percentage having Coroners Post Mortem	Total Percentage having Post Mortem
1993	41.1	8.2	49.3
1994	49.0	5.9	54.9
1995	38.5	4.8	43.3
1996	51.8	5.0	56.8
1997	46.5	7.7	54.2
1998	50.9	5.6	56.5
1999	44.7	5.0	49.7
2000	41.8	5.3	47.1
2001	33.2	5.9	39.1

The regional co-ordinator is aware from the RRFs returned in 2002 that apart from coroner's post mortems no paediatric post mortems were conducted in that year. Paediatric pathologists have been directed to dealing with existing archive material and facilitating its reclamation by families. This has meant a great disservice to parents of infants stillborn or dying in 2002. Steps have been

taken recently to provide a 'limited post mortem' service pending the re-establishment of a regular paediatric pathology service within the next few months.

Among hospital post mortems the post mortem rate was highest for stillborn infants but even here it failed to reach 50% and for liveborn infants who die it was of the order of 20% (Table 3.2).

Table 3.2 Percentage of Deaths having Post Mortem by Category of Death 2000/2001

Category of Death	Hospital Post Mortem		Coroner's Post Mortem	
	2000	2001	2000	2001
Late Fetal Loss (54,47)	48.1	34.0	0	0
Stillbirth (93,112)	52.7	48.2	1.1	0
Early Neonatal Death (70,72)	34.3	23.6	1.4	5.6
Late Neonatal Death (20,19)	20.0	26.3	15.0	21.1
Post Neonatal Death (27,36)	18.5	8.3	33.3	25.0

(,) Total NI CESDI deaths in 2000, 2001

There was recorded failure to request a post mortem in 22.4% of deaths compared with 16% in 2000. In a further 16.8% it is not known whether or not permission was requested but it is known through checks with pathology departments that post mortem was not performed (Table 3.3).

Table 3.3 Post Mortem Status All Deaths 2000/2001

Post Mortem Status	2000		2001	
	No	%	No	%
Post Mortem Held	110	41.8	95	33.2
Not Sought	42	16.0	64	22.4
Permission Refused	65	24.7	62	21.7
Coroners Post Mortem	14	5.3	17	5.9
*Not Known	32	12.2	48	16.8
Total	263	100.0	286	100.0

* Not known whether permission for post mortem examination was requested or not. It is known that post mortem was not performed.

Whether failure to request a post mortem was due to clinicians' awareness of the difficulties the paediatric pathology service was experiencing as a result of the burden of work associated with the Human Organs Inquiry, or to a high level of professional confidence in clinical findings, or to reticence in approaching parents amidst a climate of public and professional discord/loss of confidence is not known.

Professional confidence in clinical findings may be misplaced. Earlier CESDI reports have reported how the post mortem can reveal new clinically relevant information in over 20% of cases⁷.

In 2000 permission for post mortem was known to have been requested in 175 cases (66.5%) and over one third (37.1%) of these requests were refused. In 2001 permission was known to have been requested in 157 cases (54.9%) and 39.5% were refused.

4. Sudden Unexpected Deaths in Infancy

Sudden Unexpected Deaths in Infancy have continued to fall (Table 4.1).

Table 4.1 Sudden Unexpected Deaths in Infancy 1993-2001

Year	Total	Occurring in Neonatal Period
1993	24	5
1994	17	1
1995	10	1
1996	17	0
1997	18	1
1998	14	0
1999	11	3
2000	12	4
2001	10	2

It remains a cause for concern that many of those that now occur do so in circumstances where the sleeping arrangements or conditions in which the infant is placed are considered ill-advised⁸. These relate particularly to sleeping with an infant on a settee or armchair, or bedsharing with the infant by parents who smoke or who have recently consumed alcohol or certain drugs. The Chief Medical Officer has circulated an executive letter to professionals updating advice on these points and a new advice leaflet for parents is in preparation.

While the environment in which the infant sleeps has been identified as a risk factor for SIDS the extent to which the event can be attributed to the environment is not known nor is the degree to which social/clinical/pathological profiles of the infants may be comparable. In recognition of this latter point recent initiatives involving coroners, pathologists, paediatricians, public health consultants and police care unit officers have seen the convening of a group to develop a standard protocol for the recording and investigation of these deaths. This is to ensure that in all cases no opportunity to further our understanding is lost and also that all parents receive the fullest possible explanation of events from a senior professional with access to all relevant information.

The challenge for professionals working in maternity units and communities is to achieve a balance between promoting good infant care practice and closeness between a mother and her baby yet addressing the question of how to reach those who have proven resistant to or unaware of current health education messages.

5. The Diabetes Study

A. Background

In 1989 the St Vincent declaration stated that within 5 years the ‘outcome of diabetic pregnancy should approximate to that of the non-diabetic pregnancy’⁹.

However, surveys in England, Scotland and Northern Ireland in the late 1990s^{10, 11, 12} have shown perinatal mortality rates ranging from 18.9 to 42.8 per 1000 births, against a background rate of 7.9 per 1000, a two to five fold increased risk of perinatal death in babies of diabetic mothers. Congenital malformation rates in the same surveys range from 55 to 94 per 1000 live births, a four to ten fold greater risk. The St Vincent goal has clearly not been achieved.

In 1999 the Department of Health in England and Wales announced that its fourth National Service Framework would address Diabetes and in 2001 the NI Clinical Resource Efficiency Support Team (CREST) addressed the subject in its publication ‘Management of Diabetes in Pregnancy’¹³.

The introduction of a Diabetes Programme by CESDI was therefore a timely reflection of national interest. It would for the first time establish a baseline of diabetic pregnancy outcome across England, Wales and Northern Ireland and would help to identify areas of care that affect outcome.

B. The Denominator

The programme focuses on pregnancies in women with pre-existing diabetes, whether insulin dependent (IDDM or Type I) or non-insulin dependent (NIDDM or Type II).

For the national study a diabetic pregnancy is defined as a pregnancy in a woman who has been diagnosed to have diabetes mellitus at least one year before her estimated delivery date (EDD).

This was intended to exclude women with:

- Absence of Diabetes when not pregnant – this is gestational diabetes. Inconsistency in the definition of gestational diabetes due to variations in screening and diagnostic criteria throughout the UK would hinder the determination of a homogeneous denominator.
- ‘Diabetes’ arising for the first time during this pregnancy. This could be gestational diabetes, Type I or Type II diabetes. Whatever the proven type once the pregnancy ends, pre-conceptual diabetic care could not have occurred and data interpretation would be affected.

However, professionals in N Ireland were keen to use the opportunity afforded by the main study to collect information on the prevalence and outcome of pregnancies affected by gestational diabetes. The NI study therefore also developed a modified version of the data collection instrument used in the Type I/Type II study to collect information on gestational diabetes.

The main components of the Enquiry Programme have already been described in the previous NI CESDI report but are shown here in Appendix 2.

A pilot study was conducted from September-December 2001 and the definitive study data collection began in March 2002.

In the nine-month period March 1st 2002-November 30th 2002 notifications of 56 pregnancies in women with Type I or Type II Diabetes have been received from 6 maternity units in the province. 53 deliveries to diabetic women have been reported in that period. Two infants were lost before 20 weeks, 0 infants have been lost in the late fetal period (20-23 wks gestation), 0 infants have been stillborn and 2 have died in the neonatal period. One of these deaths had neural tube and other defects.

Reporting of the extent to which the obstetric and neonatal care met recommended standards regarding the structure, organisation and delivery of services awaits the more detailed approach of Confidential Assessment.

C. *The Confidential Assessment*

The National Diabetes Project Professional Advisory Group (PAG) reviewed the various methods used for confidential enquiries and concluded that multi disciplinary panel assessments, conducted according to a standard process and with access to the full set of anonymised clinical records were to be the method of choice.

To maintain confidentiality and objectivity, cases would be enquired out of Region, – allocated from a national pool.

The PAG also noted that:

- Guidelines would be issued regarding the composition of enquiry panels and the role of a panel member.
- Panel chairmen (probably 2 per region) would receive training in facilitation skills to ensure standardisation of approach in an enquiry panel.
- A representative from Diabetes UK would be on each panel.

The detail of the issues and standards related to maternity and neonatal care which are to be the focus of panels deliberations and the methods by which formal consensus is to be reached at panel meetings have not yet been determined by PAG. It is envisaged that panel assessments are unlikely to commence until May/June 2003.

However, while a national document has not yet come from CESDI the local CREST publication on the Management of Diabetes in Pregnancy contains instructions and useful models for audit of the structures, process and outcome of services for pregnant women with diabetes Appendix 4. It is the intention of local Diabetes specialists and the CESDI Regional Co-ordinator that a local audit using these will be facilitated through the CESDI data.

6. Confidentiality and Informed Consent

When CESDI was set up in 1992 there was an NHS directive aligning it with clinical audit. Approval of local ethical committees was not therefore required and the issue of consent was not a central concern.

Recent years however have seen an increase in public and professional sensitivity to the use of information from health records. At recent CESDI meetings co-ordinators have raised concerns regarding the need for formal consent. It was agreed that, even when notes are anonymised it was good practice to seek consent unless there were compelling reasons otherwise. The Steering Group for the current CESDI Diabetes Enquiry is exploring the implications of this with a pilot exercise in one CESDI region (not NI) to examine the effects of seeking consent on the workload and the impact on the Enquiry programme.

In 1997 the Department of Health and Social Services (NI) had issued guidance entitled ‘The Protection and Use of Patient and Client Information’¹⁴.

This guidance clarified how and when personal information could be shared, stressed the need to make patients and clients aware of how their information was used and confirmed the common law duty of confidence.

Since then the introduction of new Data Protection and Human Rights legislation together with guidance from different professional bodies have meant that the rights of individuals to be made aware of, and have a say in, how their information is used are given much stronger emphasis.

An amended version of the 1997 publication was published in 1999 but in the light of an uncertain and changing situation the NI Department of Health, Social Services and Public Safety has in June 2002 produced the consultation paper “Health and Personal Social Services – Protecting Personal Information”¹⁵. This paper seeks to set the debate surrounding data protection and confidentiality in context, to highlight current problems, pose a number of questions and seek views on a number of possible solutions. It suggests that implied consent would be valid when processing service user information for the purpose of assessing and improving the quality of care and treatment.

CESDI in Northern Ireland has responded to the questions posed in the paper.

The forthcoming introduction in NI of a new Health and Care Number (HCN), being developed within the Unique Patient and Client Identifier (UPCI) Project will help resolve the potential conflict between protecting the privacy of individual service users and the wider benefits to society which can accrue from the use of personal information in eg the field of public health. It is not however expected that this number will be in general use before 2004.

Current practice within CESDI seeks to ensure that data are collected and processed in accordance with the various requirements of the several Acts, Guidelines, Policy documents and Common Law which relate to fair and lawful practice.

We continue however to have concerns about the lack of clarity surrounding this issue and await with interest the publication of the DHSSPS paper arising from the consultation document.

7. CESDI – CEMACH Update

Readers are aware that CESDI in Northern Ireland was established and funded by the NI Department of Health and Social Services. The organisation of the enquiry in the province has mirrored that of CESDI in England and Wales and information from N Ireland has contributed to the national enquiry reports.

In 1999 the National Institute for Clinical Excellence (NICE) received from the Department of Health (England and Wales) responsibility for the four Confidential Enquiries

- i) Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI)
- ii) Confidential Enquiry into Maternal Deaths (CEMD)
- iii) Confidential Enquiry into Perioperative Deaths (CEPOD)
- iv) Confidential Enquiry into Suicide and Homicide by People with Mental Illness (CISH)

Following consultation on proposals for the development and management of such enquiries a number of decision with major implications for CESDI in England and Wales, and indirectly for N Ireland, were announced in November 2001. Chief among these were:

- CESDI and CEMD in their present form would terminate by 31st March 2003.
- A new Confidential Enquiry for Maternal and Child Health (CEMACH) would be developed. The remit of this to extend to children under 16 yrs. In due course, the scope for extending the enquiry methodology to near misses and morbidity would be considered.
- NICE would appoint a Chief Executive for CEMACH with effect from 1st April 2002 to take responsibility for the transition of CESDI and CEMD in their final year of operation and lead and manage CEMACH in its first year.
- Processes and methodology for CEMACH to be agreed with NICE.
- Total budget would be significantly reduced.
- CEMACH would interact fully with the other Confidential Enquiries.
- A central Confidential Enquiries Advisory Committee (CEAC) would be established. Northern Ireland and Scotland would have observer status at meetings of this body.

Among the recommendations made in the report, key statements recorded were:

“if it is to retain the respect and credibility on which the effectiveness of the present Enquiries depends, it should continue to be seen as independent of government and other vested interests”

“should be a flexible Enquiry instrument deployable to an adaptable programme of study topics”

“unifying theme would be national intelligence of outcomes from NHS activity”

“index conditions would be determined by government priorities, public concerns and assessment of technologies”

“the guarantee of confidentiality offered to clinicians by the present Enquiries is effective in making available valuable information that would not otherwise be obtained and should continue”

“the guarantee of confidentiality can and should be combined with feedback of assessment of case management to individual clinicians and clinical teams”

“feedback from Confidential Enquiries should be kept separate from systems of local audit and access by third parties should be strictly prescribed”

“assessment of cases should be evidence-based rather than normative”

A CEMACH Constitution and Structure paper detailing the setting up of the CEMACH governing body and the rolling forward of the financial and personnel arrangements which require to be in place in E&W if CEMACH is to start as planned in April 2003 is being presented to NICE for approval in January 2003 (see below).

The effect on Northern Ireland CESDI of these major changes to CESDI in England and Wales is as yet unclear but the paper contains the following paragraph.

“NORTHERN IRELAND

Northern Ireland is not large enough to support a viable CEMACH Regional Office in the manner outlined above for the English Regions with equivalent levels of funding on a population basis. However the Northern Ireland government has historically provided significant funding for its perinatal survey team. The national CESDI and perinatal survey work have been carried out interchangeably within the team. The simplest approach may be for Northern Ireland to participate in the work of CEMACH by contributing a sum based pro-rata to the headquarters’ cost and by agreeing to fulfil the regional role outlined above.

Consultation Question for stakeholders in Northern Ireland: Do you agree that Northern Ireland should participate in CEMACH by contributing a proportion of the new Enquiry’s headquarters’ cost and by agreeing to fulfil the role outlined in this document for the English Regions?

Neither the remit of NICE nor the managerial authority of the CEMACH Chief Executive extends here.

It is clear however that working together with England and Wales in CEMACH would offer organisational and epidemiological benefits.

The announcement in June 2002 by the N Ireland Health Minister of new arrangements to improve quality in the NHS¹⁶ did not make any direct reference to CEMD, CESDI or CEMACH but did say that the new arrangements would include:

“A formal link with the two English bodies, the National Institute for Clinical Excellence and the Social Care Institute for Excellence, to allow us to share their arrangements and experience”.

Discussions between DHSSPS and NICE about how this formal link might be established have been initiated at senior administrative level but it will be some months before any detail about any CEMACH/N Ireland relationship can be expected.

In the interim the Regional Co-ordinator remains in close contact with the CEMACH Chief Executive and anticipates that NI will maintain CESDI and CEMD in their present arrangements and activities here until the administrative issues are resolved.

UPDATE FEBRUARY 2003

In January 2003 the NICE Board approved that CEMACH be formally constituted as a consortium of Royal Colleges with its own independent Board. The Colleges involved will be the Royal College of Obstetricians and Gynaecology, the Royal College of Midwives and the Royal College of Paediatrics and Child Health. The RCOG is to host the consortium and be the ‘lead’ for managerial purposes.

This clears the way for N Ireland to ‘sidestep’ NICE and contract directly with the RCOG to ‘service’ CEMACH (and pay pro rata for the service along with the regions of England and Wales). Details of the arrangement are currently being finalised but we are on stream to become part of National CEMACH on April 1st.

It is expected that the number of Colleges involved in the CEMACH Board will soon be increased to include some other relevant groups eg the Royal College of Pathologists and Faculty of Public Health Medicine.

8. Developing Quality

The experience of co-ordinating CESDI in N Ireland since 1992 has highlighted the shortcomings of using the Confidential Enquiry approach to quality of care measurement without having in place a range of other epidemiological and clinical measures of quality in relation to maternal and child health. The opportunity for improving quality of care has been limited by the isolation of CESDI from other bodies concerned with policy formulation, maintenance and development of information bases, organisation of professional education and training, clinical audit, public health initiatives, etc.

Links have been established with staff working in a number of these fields and CESDI has given support to the development of some specific initiatives and the audit of others. These included:

- A Northern Ireland Perinatal Information (**NIPi**) Project

The aim of this project involving multidisciplinary clinical and data management staff, was to consider how the current child health information system might be developed to support a range of activities which aim to improve understanding of perinatal mortality and morbidity and maximise the opportunity for reduction in current rates. Such activities include:

- a) Core public health functions including monitoring of health and disease surveillance.
- b) Risk assessment/risk management.
- c) Clinical audit, service evaluation, and measurement of outcomes.
- d) Service planning and development.
- e) Antenatal, neonatal and child health screening programmes.

- Neonatal Intensive Care Outcomes Research and Evaluation (**NICORE**)

This multidisciplinary audit group aims to improve the quality of care for the newborn and to identify and support research priorities in this field.

- Exploring the establishment of links with **BINOCAR** (British Isles Network of Congenital Anomaly Registers) and the development of a Northern Ireland Register.
- Participation in an Audit of Neonatal Hospital **Transfers**.
- Collaboration in a project “Monitoring **Inequalities** in pregnancy outcome in Northern Ireland with National Comparisons.

In addition CESDI has informal links with a number of other individuals and groups which have been collecting/using information about mothers and infants at unit/area/regional level to inform certain audit or research topics. However, all these activities remain divorced from any overall plan or perspective on priorities for quality assurance.

The unco-ordinated development of projects and the absence of agreed strategies for ensuring any necessary dissemination of evidence, improvement in training or change in clinical management have diminished the 'front line impact' of the efforts which many individuals and groups have invested in seeking to improve childhood outcomes.

Those involved in the Perinatal Information Project have drafted proposals which build on the various developments and initiatives currently going on¹⁷ and identify priority developments (Appendix 5). These envisage the development of an organisation which would address the causes of adverse perinatal outcomes, identify relevant research topics, and inform and foster the implementation of effective care. It is suggested that this might be through the establishment of eg a multi-professional NI Perinatal Institute or Regional Reproductive and Child Health Office possibly with a joint NHS/Academic base.

The range and type of work to be undertaken by such an institution and how it would be done would reflect the priorities and values both of professionals and others. A range of staff expertise and skills would facilitate a broadly based approach to questions of quality of care.

The aim would be to develop an agreed programme of work which incorporated 'core' activities eg production of annual perinatal tables and trends, along with a range of 'specific topics' which might relate to national initiatives eg CEMACH, or to local audit programmes eg NICORE. The flexibility to commission or undertake work on topics of particular local interest, importance or urgency would be important as would an outward looking perspective maintaining close links with individuals and organisations both within and outside the NHS in NI and elsewhere.

The most immediate objective would be to address the shortcomings of existing information systems by placing appropriate information staff to manage systems locally and by ensuring effective linkage between systems.

These aims reflect many of the key elements of the vision for CEMACH noted in a recent consultation document from NICE (Appendix 6).

9. Near Misses

The Confidential Enquiry approach to investigating deaths has proved a valuable method of identifying and addressing situations in which clinical care may have fallen short of expected standards. The new CEMACH enquiry has indicated that it proposes to broaden the scope of enquiry to “cover a wide programme including mortality, morbidity and near misses for mothers, babies and children”.

A number of recent publications have emphasised the importance of developing processes which help organisations and individuals to manage, report, analyse and learn from incidents other than those resulting in the death of a patient^{18, 19, 20}.

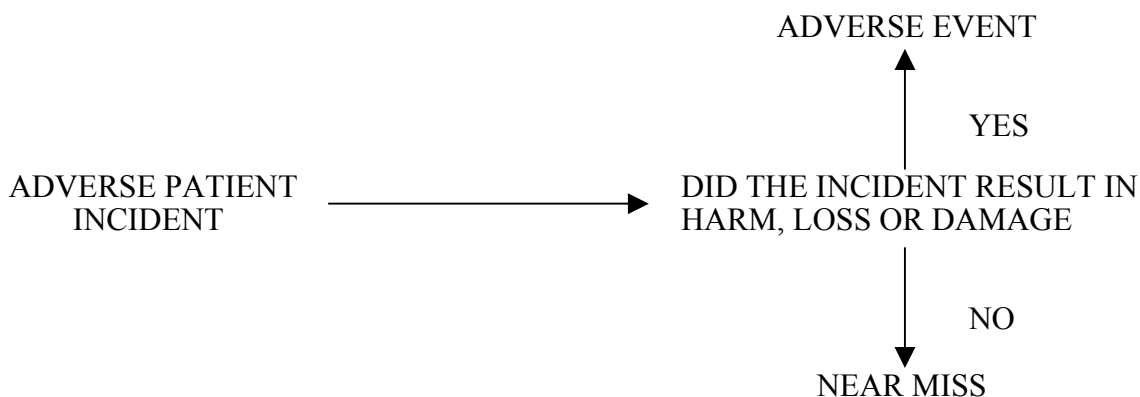
The expectation is that investigating near misses can allow us to learn a lesson ‘free’ and that failure to do so may result in having to learn it through expensive litigation.

Near misses come under the term ‘adverse patient incidents’. In England and Wales a National Patient Safety Agency has been established to collect and analyse incidents and other patient safety information and provide timely and relevant feedback in a way that promotes learning and risk reduction through environmental and/or systems changes, and/or changes in organisations, management or clinical practice.

In NI the Clinical Governance agenda reinforces the need for sound clinical risk management. This entails a systematic approach to risk assessment and proactive risk management in addition to the reactive process of incident management.

The term ‘adverse patient incident’ has been defined as ‘any event or circumstance arising during NHS care that could have or did lead to unintended or unexpected harm, loss of damage’.

Those incidents that did lead to harm are referred to as ‘adverse events’. Those incidents that did not lead to harm, but could have, are referred to as near misses.



Apart from incident reporting a number of other means of detecting adverse events have been described²¹. All require an investment of time and money. Without these, the development of mechanisms to identify and deal with clinical risk will present a risk to current clinical activity. It is imperative that units/trusts are able to have a designated person or persons working with clinicians and management to establish an effective local policy which reflects national requirements and standards for detecting and documenting relevant incidents.

The definition of Near Miss remains unclear. This must be addressed before CEMACH can move forward to the wider programme proposed by NICE.

10. Confidential Assessments and their Impact

The need for extensive discussions involving CESDI with the Department of Health, NICE and a wide range of professional and other bodies meant that, as already mentioned, the final national analysis of data from the 27/28 week project and the commencement of the confidential enquiry element of the diabetes project were delayed. The national report on Project 27/28 is now scheduled to appear in late April 2003.

This hiatus in enquiry activity has afforded an opportunity to reflect on the themes of some of the comments and criticisms which have recurred during previous assessments, to reinforce some of the recommendations and to note some important developments which CESDI might claim to have had a part in fostering.

A feature of confidential enquiries to date is that there is no mandatory compliance with recommendations and no systematic monitoring of their uptake. It was usually left to individual services or Trusts to pick up and implement specific recommendations which appeared to them to be relevant to their own function or sphere. CESDI might therefore be best judged as a catalyst aiming to initiate a reaction by other bodies which have the educational, organisational or managerial responsibilities for delivering care to the highest possible standards.

It is anticipated that this rather *laissez faire* response will be changed with the introduction of CEMACH. It was stated by NICE that the new arrangements for selecting conditions for confidential enquiry should take account of national priorities and that recommendations arising from enquiry reports should have similar status to other NICE guidance.

Themes or topics which have been of particular note in earlier reports have included:

A. Care During Labour

The 4th Annual Report highlighted the fact that at least half of labour related deaths occurring in 1994 and 1995 were associated with sub optimal care that was likely to have contributed to the death²². It was gratifying to see the launch in 2001 of two national guidelines for this specific area; one on Induction of Labour and the other on the use of Electronic Fetal Monitoring^{23, 24}. The findings of CESDI had contributed to the successful bid by the Clinical Effectiveness Support Unit at the Royal College of Obstetricians and Gynaecologists (RCOG) to produce these documents. Information in the 4th and 5th Reports was important in prompting the need for a Second Report from the RCOG on Minimum Standards of Care in Labour²⁵. This report covered organisation, staffing levels, staff roles, training, accreditation and continuing education, developing standards and facilities and equipment. Many of the recommendations reflected those of CESDI.

B. Record Keeping

Almost all assessment panels have drawn attention to deficiencies in clinical records, with poor and illegible case notes being a significant part of the problem. This was the subject of comment in one third of all enquired cases. The major problem identified from the comments was failure to document events adequately (Table 10.1).

Table 10.1 Problems with record keeping identified from comments made by the panels

	No of comments Where problem Mentioned	% of all problems (n=210)
Insufficient detail/No plan of care	97	45%
Absent dates, times and signatures	29	14%
Missing documentation	27	13%
Errors and inaccuracies/retrospective additions	27	13%
Badly organised notes	16	8%
Illegible hand-writing	14	7%
Total number of problems mentioned	210	100%

This has significant medico-legal consequences since the approach of “if its not recorded, it has not been done” is generally adopted.

All local units have indicated that their audit programmes have included an audit of clinical notes. The leads from the UK Central Council for Nursing, Midwifery and Health Visiting and the NHS Executive on record keeping have already been commended^{26, 27}. Readers may be reminded of the summary of the guidelines (Appendix 7) and its use as a checklist in audit exercises may be useful. Methods of auditing the quality of the clinical content should also be addressed.

Not just the content of records has been criticised. The structure, organisation, colour, fragility and methods for storage/retrieval have all on occasions made difficulties in undertaking assessments. A recent report from the NI Audit Office²⁸ also highlighted how these structural and organisational shortcomings can jeopardise the mounting of a defence in cases of litigation and, more directly, the delivery of appropriate clinical care.

C. **Communication**

Good communication is an essential component of the transfer of relevant, accurate, timely clinical information between professionals and of the trust between professionals and parents. National and local CESDI reports have repeatedly noted deficiencies in this area.

If we consider the different purposes of communication ie creating a good interpersonal relationship, relaying and exchanging information, and making treatment related decisions it is clear that different skills are needed at different stages of care. The urgency of making effective communication in different contexts needs to be considered eg communication immediately before and during labour is likely to be focused on treatment-related decision-making and information exchange but in the context of acute and emergent demands on those involved.

It was noted that the most common time for communication errors between staff was at times of shift changes or when responsibility for care was being transferred.

Few trials of strategies to improve communication/information exchange have been reported but the 8th Annual CESDI Report³ has noted certain criteria for improving communication, clarifying responsibility and maintaining or raising standards of education

and learning (Appendix 8). These reflect the specific standard for Maternity Care set by the Clinical Negligence Scheme for Trusts in England and Wales²⁹.

There is evidence that practice has changed³. Communication channels have been formalised rather than being left to custom and habit; the quality of written communication is now subject to regular audit. Written policies for managing key conditions can be found in labour wards and these are now becoming referenced and reviewed at intervals of 3 years or less. Formal training for staff in CTG interpretation and ‘fire drill’ style training programmes for the management of rare emergencies such as shoulder dystocia and eclampsia have been important in building staff competence and confidence.

It is not yet possible to state that all these changes have been adopted by every maternity and neonatal unit in Northern Ireland nor would it be reasonable in the short term to expect their adoption to lead to a reduction in mortality or in clinical negligence claims since the latter may not be resolved for years after the event.

However the evidence from CESDI provides a basis and a direction for initiatives to reduce the level of untoward outcomes and improve patient care. We in Northern Ireland do not have a foundation similar to the Clinical Negligence Scheme for Trusts (CNST) in England and Wales to encourage, monitor and benchmark progress in the implementation of the lessons learned but a July 2002 letter to Chief Executives of Health & Social Services Boards following responses to the Ministerial Document “Best Practice – Best Care”:- “has set out structures and processes to be developed within the context of risk management, which will eventually encompass all aspects of governance³⁰. CESDI has had a part in developing and promoting the standards – the implementation of ways to ensure their universal establishment and maintenance is expectantly awaited.

D. Information Systems

Good quality information is essential to decision making but there are substantial shortcomings in national statistics relating to maternity and infant care.

From the beginning of CESDI this has been the subject of comment in the National and the Northern Ireland Reports.

Most importantly, the absence of denominator information for many of the variables collected by CESDI precluded any assessment of risk.

At a local level, the experience of tracing items of information missing from a returned RRF raised awareness of the number of agencies collecting information on mothers and infants and their variation with regard to the definitions used, the quality of the information, and its usefulness for decision making. The absence of linkage between the various sources led to enormous duplication of effort.

In 1998 CESDI(NI) commissioned a report on routine perinatal reporting in Northern Ireland. This report recommended that:

- i) A perinatal report for Northern Ireland should be published annually.
- ii) An analytic database should be established, formed of data abstracts from several existing stand-alone systems including the Child Health System (CHS), CESDI and Neonatal Intensive Care, Outcomes Research and Evaluation (NICORE) databases.

This report was considered by the Chief Medical Officer and Directors of Public Health. With the encouragement of the CESDI Regional Co-ordinator they agreed that some resources from CESDI might be used to establish a **Northern Ireland Perinatal Information Project (NIPI)**. This commenced in February 2001 with the following remit:

- To take forward the development of an integrated Perinatal Information System in Northern Ireland.

The Project aims for 2001/02 were:

- To make routinely available a set of core tables using information held on CHS in the four Board areas.
- To produce a report on births and perinatal events in Northern Ireland for the years 1991-2000.

In July 2001 the project published a Northern Ireland Year 2000 report³¹ containing core regional perinatal information. Much of this information had not previously been routinely available to users. A user evaluation was carried out which showed a high degree of satisfaction and support for the report to be produced annually. The 2001 Report has now been published³². Work is ongoing to produce a 'birth trends' report for Northern Ireland which will draw together information from the Registrar General's reports, CHS and CESDI.

During 2001 the NIPI Project Board was asked to undertake further work in the light of the recent publication of a public health strategy consultation document and of reports from the National Screening Committee on antenatal and neonatal screening.

It was agreed that a service development project would be established with the following aims:

- i) To make proposals about how we could improve access to, and use of, existing perinatal, infant and child health data sources in Northern Ireland.
- ii) To make proposals regarding a system for congenital anomaly registration and reporting in Northern Ireland.
- iii) To identify any major shortcomings in perinatal, infant and child health information in Northern Ireland and where possible propose ways of addressing such issues.
- iv) To propose a longer term vision for the development of perinatal, infant and child health information services, in the context of the regional ICT strategy and other developments within and outside of HPSS.

Developments considered by the NIPI Board to be of priority have already been noted in Appendix 5. A Regional Reproductive and Child Health (RCHO) Office operating as part of a network with local Child Health Offices is a key element in the longer term vision for development.

E. Other Topics

The close links which CESDI has with the NI Neonatal Outcomes Research and Evaluation Group (NICORE) have meant that work on a number of topics which have been the subject of CESDI recommendations has been, or is being taken forward by that group.

These have included:

- A pilot audit of inter hospital neonatal transfers.
- Nosocomial infection in Neonatal Intensive Care.
- Reduction of heat loss in pre-term infants immediately after birth.
- Making information available for quality improvement and service planning in neonatal care.
- Delivery room deaths.
- Timing of Caesarean Section and Respiratory Morbidity.

In addition, CESDI has supported a successful bid by Dr John Jenkins Chairman of NICORE to undertake work with colleagues in Eire on a project entitled Evidence-Based Quality Improvement in Neonatal Care throughout Ireland.

The coverage of all Ireland by this work is particularly gratifying. Quality improvement initiatives in NI are often hampered by small numbers which may distort judgements as to causes or factors in mortality and morbidity. It is hoped that this wider collaboration may be the first of a range of projects aiming to improve outcomes for new born infants.

F. Learning from Enquiries

At the outset of any enquiry whether into deaths, adverse incidents or near misses there is an expectation that its deliberations will change things in the future and prevent a recurrence. Historically however this generally proved to be an unrealistic expectation and patterns of error were repeated. Beliefs, attitudes and values nourished a culture of blame and superficial analysis with the front line clinician often seen as the sole culprit, needing to learn some lessons.

CESDI has had a role in reminding a much wider range of individuals and organisations, many of them remote from patient care, of their role and responsibility in the causation and prevention of such events and that they must learn from them, if they are to deliver high collective performance.

Attention has been drawn to a number of barriers to such learning¹⁸ (Appendix 9). These must be acknowledged and breached before any investigation/enquiry can be deemed of value.

A 25% reduction in litigation in Obstetrics and Gynaecology in England and Wales by the end of 2005 is one of four areas for action noted in the Governments plans to improve patient safety¹⁸. This would almost certainly be an appropriate target for NI also, but since

effective systems for recording the number and cost of such legal actions in NI are not yet well developed we need first to establish the base line and to clarify the nature of the adverse events which give rise to it. Only then can we begin to develop appropriately focused risk management programmes.

The survey of Risk Management reported in the NI Audit Office's Report on Compensation Payments for Clinical Negligence²⁸ (Appendix 10) provides a useful aide memoire of risk management elements for those aiming to develop such programmes.

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12. Abbreviations

The following abbreviations have been used:

1.	BINOCAR	-	British Isles Network of Congenital Anomaly Registers
2.	CHS	-	Child Health Information System
3.	CESDI	-	Confidential Enquiry into Stillbirths and Deaths in Infancy
4.	CEMACH	-	Confidential Enquiry into Maternal and Child Health
5.	CEMD	-	Confidential Enquiry into Maternal Deaths
6.	CREST	-	Clinical Resource Efficiency Support Team
7.	CTG	-	Cardiotocograph
8.	DHSSPS	-	Department of Health, Social Services & Public Safety
9.	EDD	-	Expected Date of Delivery
10.	EFM	-	Electronic Fetal Monitoring
11.	RRF	-	Rapid Report Form
12.	HCN	-	Health and Care Number
13.	IP	-	Intrapartum
14.	IDDM	-	Insulin Dependent Diabetes Mellitus
15.	LFL	-	Late Fetal Loss
16.	LNND	-	Late Neonatal Death
17.	NI	-	Northern Ireland
18.	NIDDM	-	Non Insulin Dependent Diabetes Mellitus
19.	NICE	-	National Institute for Clinical Excellence
20.	NICORE	-	Neonatal Intensive Care Outcomes Research and Evaluation
21.	NIPI	-	Northern Ireland Perinatal Information Project
22.	NK	-	Not Known
23.	PAG	-	Professional Advisory Group for National Diabetes Project

24.	PNND	-	Post Neonatal Death
25.	RCOG	-	Royal College of Obstetricians and Gynaecologists
26.	SB	-	Stillbirth
27.	RRF	-	Rapid Report Form
28.	SGA	-	Small for Gestational Age
29.	T-T	-	Twin to Twin
30.	UPCI	-	Unique Patient Client Identifier

13. Table of Appendices

1. Rapid Report Form
2. Classifications of Death
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4. CREST Draft Audit Design
5. Priority Developments for Perinatal Information Project
6. Vision for CEMACH
7. Principles of Record Keeping
8. Criteria for:
 - a. Communication and Responsibility
 - b. Education and Learning
9. Barriers to Organisational Learning
10. Survey of Risk management in HPSS Organisations

EXTENDED WIGGLESWORTH CLASSIFICATION

- Category 1** Congenital defect/malformation (lethal or severe): Only lethal or potentially lethal congenital malformation should be included here. Serious biochemical abnormalities such as Tay Sach's disease and any known single gene defects known to have a high risk of death should be included.
- Category 2** Unexplained antepartum fetal death: Most late fetal losses should be coded here. Where a liveborn baby dies due to problems during the antepartum period, code this as 'other specific causes'.
- Category 3** Death from intrapartum 'asphyxia', 'anoxia' or 'trauma': This category covers any baby who would have survived but for some catastrophe occurring during labour. These babies will tend to be normally formed, stillborn or with poor Apgar scores, possible meconium aspiration or evidence of acidosis. Very premature infants (those less than 24 weeks gestation) may be asphyxiated at birth, but should not be entered in this category as a rule.
- Category 4** Immaturity: This applies to livebirths only, who subsequently die from structural pulmonary immaturity, surfactant deficiency, intra ventricular haemorrhage, or their late consequences - including chronic lung damage.
- Category 5** Infection: This applies where there is clear microbiological evidence of infection that could have caused death, eg maternal infection with Group B streptococci, rubella, parvovirus, syphilis etc, or in the case of a baby dying with overwhelming sepsis.
- Category 6** Due to other specific causes: Use this if there is a specific recognisable fetal, neonatal or paediatric condition not covered under the earlier categories. Examples include:
1. fetal conditions; twin-to-twin transfusion and hydrops fetalis;
 2. neonatal conditions; pulmonary haemorrhage, pulmonary hypoplasia due to prolonged loss of liquor (primary hypoplasia being classed as a malformation), persistent transitional circulation (in the absence of infection, aspiration or surfactant deficiency), blood loss unassociated with trauma (eg vasa praevia);
 3. paediatric conditions; malignancy and acute abdominal catastrophe (such as volvulus without antecedent congenital malrotation).
- Category 7** Due to accident or non-intrapartum trauma: Confirmed non-accidental injury should be coded here. If only suspected code as a sudden unexpected death cause unknown (category 8).
- Category 8** Sudden infant death, cause unknown: This will include all infants in whom the cause is unknown or unsuspected at the time of death. Modification due to Post Mortem information should be notified later.
- Category 9** Unclassifiable: To be used as a last resort. Details must be given if this option is ticked.

APPENDIX 2B

DEFINITION OF THE TERMS USED IN THE OBSTETRIC (Aberdeen) CLASSIFICATION

CONGENITAL ANOMALY. Any genetic or structural defect arising at conception or during embryogenesis incompatible with life or potentially treatable but causing death.

ISOIMMUNISATION. Death ascribable to blood group incompatibility, rhesus (3) or non-rhesus (4).

PRE-ECLAMPSIA. Diastolic blood pressure of 90 mmHg or more on two separate days after 20 weeks gestation (140 days) with significant proteinuria in the absence of existing hypertensive disease prior to pregnancy. Without APH (5) or with APH (6).

ANTEPARTUM HAEMORRHAGE (APH), after 20 weeks gestation (140 days) whether revealed or not, excluding antepartum haemorrhage secondary to pre-eclampsia (which is classified under pre-eclampsia). Minor degrees of haemorrhage at the start of labour (a show), and haemorrhage due to a cervical erosion or polyp should be ignored, but significant or recurrent bleeding of uncertain origin that is fairly closely followed by pre-term labour should not be ignored.

MECHANICAL. Any death from uterine rupture and those deaths from birth trauma, or intrapartum asphyxia that are associated with problems in labour such as disproportion, malpresentation, cord prolapse, cord compression, or breech delivery in babies of 1000g or more. If there is no evidence of difficulty in labour, deaths from asphyxia or trauma should be classified as unexplained. Antepartum deaths associated with cord entanglement in the absence of strong circumstantial evidence that cord compression caused death (eg fetal death soon after external version) should also be classified as unexplained.

MATERNAL DISORDER. Include maternal trauma (such as a road traffic accident), diabetes, appendicitis, and cardiac disease etc, if severe enough to jeopardise the baby. Include significant renal disease or essential hypertension known to be present before pregnancy. Also include symptomatic and asymptomatic maternal infection when this resulted in the death of the baby.

MISCELLANEOUS. Specific fetal and neonatal conditions only. Do not include conditions directly ascribable to prematurity or anoxia before birth, because these deaths are attributable to the relevant underlying obstetric disorder or are unexplained (see below). Include, however, specific fetal conditions (eg twin-to-twin transfusion) or neonatal conditions (eg inhalation of milk) where these are not directly ascribable to intrapartum anoxia or pre-term delivery. Include, also postnatally acquired infection, except in babies of less than 1000g; here the reason for the ventilator dependency or low birthweight is the codeable factor.

UNEXPLAINED. Deaths with no obstetric explanation, including unexplained antepartum stillbirths, deaths resulting from unexplained pre-term delivery (including hyaline membrane disease, intraventricular haemorrhage, etc) and cases of intrapartum anoxia or trauma if the baby weighed less than 1000g at birth or delivery without any obvious associated mechanical problem. Cases should be sub-classified into those babies weighing 2500g or more (20) and those of less than 2500g (21) at birth.

UNCLASSIFIABLE. Cases where little or nothing is known about pregnancy or delivery and that cannot be fitted into any of the above categories. Use this category as sparingly as possible.

OBSTETRIC (Aberdeen) CLASSIFICATION

Categories at the head of the list take priority over those lower down. Only ONE answer applies - **it is the lowest numbered category that adequately describes the death.**

Code	Category
	Congenital anomaly:- any structural or genetic defect incompatible with life or potentially treatable but causing death.
1.	Neural tube defects
2.	Other anomalies
	Isoimmunisation:- death ascribable to blood group incompatibility
3.	Due to Rhesus (D) antigen
4.	Due to other antigens
	Pre-eclampsia
5.	Without APH
6.	Complicated by APH
	Antepartum Haemorrhage (APH)
7.	With placenta praevia
8.	With placental abruption
9.	APH of uncertain origin
	Mechanical
10.	Cord prolapse or compression with vertex or face presentation
11.	Other vertex or face presentation
12.	Breech presentation
13.	Oblique or compound presentation, uterine rupture etc
	Maternal disorder
14.	Maternal hypertensive disease
15.	Other maternal disease
16.	Maternal infection
	Miscellaneous
17.	Neonatal infection
18.	Other neonatal disease
19.	Specific fetal conditions
	Unexplained
20.	Equal or greater than 2.5kg
21.	Less than 2.5kg
22.	Unclassifiable

APPENDIX 2C

DEFINITION OF THE TERMS USED WHEN CLASSIFYING THE MAIN FETAL AND NEONATAL FACTORS INVOLVED IN PERINATAL DEATH	FETAL AND NEONATAL FACTOR CLASSIFICATION
	Categories at the head of the list take priority over those lower down. Only one number can be applied to any one death.
	Code Category
CONGENITAL ANOMALY. Any genetic or structural defect arising at conception or during embryogenesis incompatible with life or potentially treatable but causing death. Separate out deaths associated with a neural tube defect and death caused by chromosomal, cardiac or renal abnormality from deaths due to other miscellaneous or multiple abnormalities	Congenital anomaly:- any structural or genetic defect incompatible with life or potentially treatable but causing death.
ISOIMMUNISATION. Death ascribable to blood group incompatibility.	1 Chromosomal defect
ASPHYXIA BEFORE BIRTH (whether the baby is stillborn or not). Specify whether the insult originated before (8) or during (9) labour. All non-malformed stillborn babies are arbitrarily classified as dying of asphyxia unless death is due to a specific recognisable condition such as idiopathic hydrops fetalis, twin-to-twin transfusion etc, or there is evidence of malformation, isoimmunisation, trauma or infection. It would be assumed that asphyxia developed during labour unless there is reasonable evidence to the contrary if the baby was alive when labour started.	2 Inborn error of metabolism
BIRTH TRAUMA. Death during or after birth due to rupture of the liver, splenic avulsion, fracture/dislocation of the occipital bone, or due to serious damage of the falx, tentorium, great cerebral vein or cervical spine during delivery. Where there is clinical or Post Mortem evidence of both asphyxia and trauma, death should be ascribed to asphyxia before birth (see above) unless it is clear that trauma is the more important factor.	3 Neural tube defect
SEVERE PULMONARY IMMATUREITY. Babies with structural immaturity of the lung so gross as to render sustained ventilatory support unsatisfactory from the outset. Such babies are almost always less than 27 weeks gestation at birth.	4 Congenital heart defect
HYALINE MEMBRANE DISEASE (HMD). Death due to pulmonary immaturity or surfactant deficiency or its late consequences. Specify whether there was significant periventricular bleeding (or infarction) (13) or secondary infection (14) as well.	5 Renal abnormality
INTRACRANIAL HAEMORRHAGE (or infarction). Exclude intraventricular and periventricular haemorrhage associated with potentially lethal HMD (12-14), and other haemorrhage secondary to trauma (10) or asphyxia before delivery (8 or 9). Separate deaths due to intraventricular or periventricular haemorrhage or infarction (15) including periventricular leukomalacia (conditions that are normally associated with pre-term delivery) from other intracerebral haemorrhages (such as subarachnoid or cortical haemorrhage) or cerebrovascular occlusion of the type more normally seen in babies born at term (16).	6 Other malformation
INFECTION (including necrotising enterocolitis). Include antepartum as well as postpartum infection but exclude infection secondary to treatment for HMD. Separate deaths from necrotising enterocolitis from other deaths, and indicate, in the remaining cases, whether the infection was thought to have been acquired before the onset of labour, during delivery, or after birth. Specify site and organism.	7 Isoimmunisation
MISCELLANEOUS. Death due to other specific fetal and neonatal conditions. Specific fetal conditions include tumours, isoimmunisation, unexplained hydrops fetalis and death due to the twin-to-twin transfusion syndrome. Specific neonatal conditions include aspiration of milk or gastric contents, unexplained pulmonary haemorrhage, pulmonary hypoplasia due to prolonged loss of liquor (primary hypoplasia being classed as a malformation), persistent transitional circulation (in the absence of underlying aspiration or surfactant deficiency), and blood loss unassociated with trauma.	8 Asphyxia before birth
UNCLASSIFIABLE OR UNKNOWN. Other inadequately documented deaths, unattended deliveries, unexpected and unexplained cot deaths (22) unattended deliveries not otherwise classifiable (23) and other undocumented death (24).	9 Antepartum asphyxia
	10 Intrapartum asphyxia
	11 Birth trauma
	12 Severe pulmonary immaturity
	13 Hyaline Membrane Disease HMD)
	14 Hyaline Membrane Disease
	15 HMD with IVH
	16 HMD with infection
	17 Intracranial Haemorrhage (+ Infarction)
	18 Intraventricular Haemorrhage (IVH)
	19 Other intracranial bleeding
	20 Infection
	21 Necrotising enterocolitis
	22 Antepartum infection
	23 Intrapartum infection
	24 Postpartum infection
	25 Miscellaneous
	26 Unclassifiable or unknown
	27 Cot death
	28 Unattended delivery
	29 Other undocumented death

COMPONENTS OF DIABETIC PREGNANCY PROGRAMME

PROGRAMME 1ST JANUARY 2002 – 30 JUNE 2003

STAGE 1 – THE DENOMINATOR

This will entail:

A. Notification of all diabetic pregnancies

This will be done using pregnancy notification forms which will be placed in all antenatal clinics.

B. Notification of all deliveries to diabetic mothers

This will be done using delivery notification forms placed in:

1. All Maternity Units.
2. All Gynaecology Units – this will aid capture of early pregnancy losses. It also will identify diabetic women who have not yet attended an antenatal clinic and who have not been recruited to the study by the pregnancy notification form.

C. Outcome of Diabetic Pregnancy

This will be done using Outcome Notification forms, to be completed at 28 days post delivery, indicating the status of the infant. The Regional Co-ordinator will liaise with neonatal units, health visitors and child health information systems to acquire this information.

STAGE 2 – THE CONFIDENTIAL ENQUIRY

This will include:

- A.** Enquiries on all stillbirths and neonatal deaths in infants born between January 1st 2002 and June 30th 2003 to mothers with diabetes.
- B.** Enquiries on a selection of surviving infants born in that period to mothers with diabetes.
- C.** The incorporation of audit tools used in the Scottish Survey of 1999.
- D.** The participation of diabetes physicians and specialist nurses in assessment panels, in addition to the current mix of staff from obstetrics, paediatrics and pathology.



DRAFT AUDIT DESIGN

Organisational arrangements for the management of pregnancy in diabetic women (1st audit project in the rolling audit programme)

Title:	Review of the services available within Trusts offering obstetric services for pregnant diabetic women.
Aim:	Identify those Trusts/hospitals which are able to offer the best possible care.
Intended outcome:	Designate Trusts which meet established criteria. Facilitate commissioners and designated Trusts to circulate to GPs and community midwives, written information on clinics in their area.
Standards:	CREST guidelines: Management of Diabetes in Pregnancy.
Sample:	All Trusts which offer antenatal care for pregnant women with diabetes.
Methodology:	Postal questionnaire to Clinical Director in Obs & Gynae <u>and/or</u> Clinical Director in Medicine.
Timescale:	Questionnaire issued in December 2001. Questionnaire returned to project co-ordinator within 4 weeks of issue. Analysis within one month of the questionnaires being returned.
Action plan:	Timeframes identified for: CREST/commissioners to identify designated Trusts. Commissioners and Trusts to notify GPs and community midwives with written information on the clinic in their area. Questionnaire to be reissued within 12 months of guidelines being issued.

Clinical Management of pregnancy in diabetic women (2nd audit project in the rolling audit programme)

Aim:

Improve maternal and fetal outcome by establish if pregnant diabetic patients have had:

- Appropriate pre-pregnancy counselling.
- Timely referral for antenatal care.
- Management by a specialist team.
- Relevant monitoring at appropriate intervals, within the minimum number of hospital visits.
- Onward referral to the regional centre, where appropriate.

Standards:

CREST guidelines: Management of Diabetes in Pregnancy.

Sample:

All pregnant diabetic patients delivered in NI between (select dates).
Patients identified through PAS/NIMATS.
Validation of sample via NICORE and HbA1C /blood glucose laboratory tests ordered by Consultant Obstetrician.

Methodology:

Retrospective case note review.
(When standardised records are introduced, it might be easiest for the manual records to be photocopied and the data extracted/correlated by one individual, with follow-up/detailed review of only the notes where unusual/abnormal results were identified.

Timescale:

Audit data collection to be agreed.
Interim report of first six months' results to clinicians by Summer 2002.
Report of first year's data to CREST/RMAG by March 2003.

Project co-ordination:

To be decided. May be by nomination of one individual to coordinate regionally.

Definitions and Instructions:

Some definitions required. These to be agreed following a regional meeting to agree details of audit.

NORTHERN IRELAND PERINATAL INFORMATION PROJECT

The five highest priority developments are (not in rank order):

1. Introduction of UPCI

This would support:

- i) Linkages between existing systems
- ii) Monitoring of health and disease surveillance
- iii) Outcome measurement
- iv) Evaluation and quality management of services
- v) Delivery and quality management of screening programmes.

2. A universal, common maternity information system which supports antenatal screening programmes, with electronic links to relevant laboratory systems.

This is essential to provide routine data to support:

- i) The delivery of maternity services
- ii) Audit and evaluation of services
- iii) Planning of services
- iv) Delivery and quality management of screening programmes
- v) Performance management.

3. Improvement in quality and usefulness/value of data which requires:

- i) The development and implementation of data standards and definitions. This would lead to improved reliability, validity and comparability of data and is likely to improve efficiency as the data collected will be more meaningful and more useful.
- ii) Support and development of informatics services and expertise. This will enable the existing data to be analysed and interpreted appropriately and therefore be more useful to a wide range of data users.

4. Development of Child Health Module of PCIS. (The system/module should support neonatal screening programmes). The existing CHS system should continue to be supported until a replacement is operational.

This is needed to support the delivery, quality management and evaluation of child health services including immunisation, neonatal screening and child health surveillance.

5. The consolidation and development of existing perinatal and child health projects/databases/enquiries and expertise. This would involve the development of a regional Reproductive and Child Health (RCH) Office which would operate as part of a network with local Child Health Offices.

The functions at the proposed RCH Office would be to:

- Produce regional reports on births and perinatal events (currently undertaken by NIPI Project). This would include analysis and reporting of routine data from existing sources within HPSS.
- Survey and report on neonatal intensive care processes and outcomes (currently carried out by NICORE – Neonatal Intensive Care Outcomes Research and Evaluation Project).

- Conduct the Confidential Enquiries into i) Stillbirths and Deaths in Infancy (CESDI) ii) Maternal Deaths. These are currently carried out by the regional CESDI Office, Boards, Trusts and the Department.
- Provide a cerebral palsy register and information service (A register is currently maintained at QUB on behalf of DHSSPS).
- Establish and maintain a congenital anomaly and information services (not currently available in Northern Ireland).
- Provide the lead role in relation to ensuring quality of perinatal and child health information within HPSS systems.
- Act as the regional quality assurance centre for antenatal, neonatal and child health screening programmes.

The main ‘customers’ of a RCH Office would be HPSS bodies and individuals and government departments.

The development of a RCH office would:

- i) Improve access to and use of existing information.
- ii) Remove duplication within the service.
- iii) Improve efficiency of information collection and dissemination.
- iv) Address important gaps in information eg congenital anomalies, (required to support the evaluation of antenatal and neonatal screening programmes, health impact assessments and research into environmental hazards.)
- v) Create a ‘critical mass’ of informatics and other expertise which would provide a regional resource for the HPSS and government departments.

FROM: CONSTITUTION AND STRUCTURE OF THE CONFIDENTIAL ENQUIRY INTO MATERNAL AND CHILD HEALTH

VISION

This paper proposes that the key elements of the vision for CEMACH are that it should:

- be an enquiry with a nationally focused programme of work
- cover a wide programme including mortality, morbidity and near misses for mothers, babies and children
- be making a clear difference to clinical practice
- be part of the everyday working lives of the clinical professionals to whom its work relates
- have a robust study methodology which enables its results to play a part in the development of national clinical guidelines
- continue to produce epidemiological analyses of deaths of mothers and babies and, in the future, children
- carry out major projects and also minor studies designed to answer specific questions
- develop mutually supportive relationships with local perinatal surveys and equivalent local bodies
- attract wider sources of funding for work which is compatible with its core enquiry programme and ethos.

INFORMATION MANAGEMENT AND TECHNOLOGY

Information Management and Technology will also be an important part of headquarters activity. CEMACH will manage the software requirements of the enquiry and the arrangements for data security. This will be essential if it is to meet the increasingly stringent legal and policy requirements in this area. CEMACH will need to submit a section 60 application for exemption from the requirement to obtain consent for the capture and storage of patient identifiable information. Approval will only be possible if CEMACH can demonstrate that it is in control of the systems which support its activity.

RELATIONSHIP OF CEMACH REGIONAL OFFICES WITH REGIONAL PERINATAL SURVEYS

CEMACH will, though, want to work in partnership with local health services. There are clear benefits in the CROs working at a local level in a close alliance with related local bodies such as Perinatal Survey Units. Local survey units can gain from an association with a national programme. CEMACH will gain from easier access to local networks and dissemination of findings.

REF: NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE: CONSULTATION DOCUMENT NOV. 2002

PRINCIPLES OF RECORD KEEPING

- legible and neat using black ballpoint pen to facilitate photocopying
- to be clear, unambiguous and concise
- to be contemporaneous, accurate, relevant and complete
- no blank spaces (if information not requested draw line through space)
- identify time of day or night 24 hour clock
- correct mistaken entries promptly and properly
- state observations and action taken clearly
- document conversations between staff or staff to patients (including advice and discussions relating to care)
- clearly record care given by another member of the health care team
- record patient/health care worker non-compliance
- sign and date every entry in professional capacity

Taken from: *Setting the Records Straight: A study of Hospital Medical Records*
by the Audit Commission – published by HMSO

Exhibit 5

... but a survey of hospital casenotes showed that standards are not always being met.



Source: *Audit Commission survey of 200 casenotes at 8 hospitals*

A. Criteria of Communication and Responsibility

The arrangements are clear concerning which professional is responsible for the woman's care at all times.

There is an agreed mechanism for direct referral to a consultant by a midwife.

There is a personal handover of care when medical shifts change

There is a labour ward forum or equivalent, to ensure that there is a clear documented system for management and communication throughout the key stages of maternity care.

There is a lead consultant obstetrician and clinical midwife manager for labour ward matters.

The labour ward has sufficient medical leadership and experience to provide a reasonable standard of care at all times.

There is a personal handover to obstetric locums, either by the post-holder or senior member of the team, and vice versa.

B. Criteria of Education and Learning

There are referenced, evidence-based multi-disciplinary policies for the management of all key conditions/situations on the labour ward. These are subject to review at intervals of not more than three years.

All clinicians should attend six-monthly multi-disciplinary in-service education/training sessions, on the management of labour, and CTG interpretation.

Emergency caesarean section can be undertaken rapidly and in a short enough period to eliminate unacceptable delay.

Barriers to organisational learning

- An undue focus on the immediate event rather than on the root cause(s) of problems
- Latching onto one superficial cause of learning point to the exclusion of more fundamental but sometimes less obvious lessons
- Rigidity of core beliefs, values and assumptions, which may develop over time – learning is resisted if it contradicts these
- Lack of corporate responsibility – it may be difficult, for example, to put into practice solutions which are sufficiently far-reaching
- Ineffective communication and other information difficulties – including failure to disseminate information which is readily available
- An incremental approach to issues of risk – attempting to resolve problems through tinkering rather than tackling more fundamental change
- Pride in organisational and individual expertise can lead to denial and to a disregard of external sources of warning – particularly if a bearer of bad news lacks legitimacy in the eyes of the individuals, teams or organisations in question
- A tendency towards scapegoating and finding individuals to blame – rather than acknowledging and addressing deep-rooted organisational problems
- The difficulties faced by people in ‘making sense’ of complex events is compounded by changes among key personnel within organisations and teams
- Human alliances lead people to ‘forgive’ other team members their mistakes and act defensively against ideas from outside the team
- People are often unwilling to learn from negative events, even when it would be to their advantage.
- Contradictory imperatives – for example communication versus confidentiality
- High stress and low job-satisfaction can have adverse effects on quality and can also engender a resistance to change
- Inability to recognise the financial costs of failure, thus losing a powerful incentive for organisations to change

Source – An Organisation with a Memory

“A Survey of Risk Management in the HPSS Organisations”

Report by Healthcare Risk Resources International – February 1999

Methodology

1. The survey assessed the 26 HPSS bodies against 12 specific risk management areas. The consultants graded the level of compliance on a score of 1 to 10 for each area in each organisation. A mark of 7 or more was equated to achieving full compliance. An overall average mark for each area was awarded, but the consultants emphasised that the averages, in some cases, disguised wide variations between organisations.

Assessment of Issues and Ratings Awarded

Issue 1 – Risk Management Strategy Documents – Rating: 5

“Almost all Trusts have produced a risk management strategy document. However, most are limited in their contents and a variety of models have been developed. It appears that greater efforts need to be made in order to ensure that the Strategy is endorsed fully by the Board of the Trust concerned and that **all** managers, clinicians and other professionals are fully aware of its contents. With regard to the four Boards and three Agencies, none of them has a contemporary, formal risk management strategy document.”

Issue 2 – Risk Profiling – Rating: 6

“There is evidence of a reasonable amount of risk assessment activity with Health and Safety issues in all the organisations, but a limited amount of risk profiling of clinical and care services on a regular basis in Trusts. Where clinical risk assessments have been made, these have tended to be one-off focused risk reviews of particular, worrying clinical services (eg maternity) where there have already been indications of the need for investigation. The emphasis required is for a rolling programme of proactive risk assessments, as part of the organisation’s normal business plan, covering every clinical, care and support service in a three-year cycle.”

Issue 3 – Incident Reporting – Rating: 7

“There is generally a good level of reporting of incidents relating to Health and Safety issues, slips, trips and falls, with a great deal of data accumulated. Whilst in some of the organisations this is converted into meaningful management information, there is an inconsistent patchwork of manual and data processing systems in use for doing so. The major deficiency relates to the very limited and, therefore, probably significant under-reporting of clinical incidents and “near misses”. A major effort is needed in almost all Trusts to improve in this area.”

Issue 4 – Patient Records – Rating: 5

“There was a low level of compliance with this issue amongst the majority of Trusts. There is no doubt that inadequately prepared patient records, or records which are unavailable when needed, contribute to unsafe clinical care and indeed, can lead to claims of negligence being lost. Accordingly, there is a real need for most Trusts to develop an explicit policy document incorporating all of the elements shown, and for there to be a system in place for the routine audit of compliance with the policy.”

Issue 5 – Clinical Audit – Rating: 5

“The consultants identified very few examples of multi-disciplinary clinical audit being used as a robust tool for risk reduction and risk control. However, there were many more instances of uni-disciplinary audit (for example, medical audit and nursing audit) and limited progress towards the development of integrated care management.”

Issue 6 – Complaints – Rating: 7

“In almost all the HPSS organisations, there were excellent systems for managing complaints from patients, their relatives and the public. Furthermore, the consultants found a lot of evidence to show that the systems are used effectively. This is not considered to be a high priority for improvement. However, because of the widening management agenda generally, it is necessary for the organisations to take steps to avoid complacency in this crucial area of risk management.”

Issue 7 - Policies and Procedures – Rating: 6

“In all the organisations visited, there were many examples of excellent policies and procedures. However, in some cases, these were noted to be out-dated and, in a few instances, related to the predecessor organisation. Whilst there is much good practice in this arena, the importance of up-to-date, easily understood, clinical and other policies, procedures, guidelines, treatment protocols and agreed standards cannot be over-emphasised in relation to risk reduction. Often, a major cause of risk is that members of staff are individually uncertain of which is expected of them, particularly in emergency situations. This can be compounded when other members of the same team have different understandings about what actions should be taken in such situations.”

Issue 8 – Communications – Rating: 6

“Generally, the HPSS organisations performed well under this heading. The majority visited had developed detailed communication strategies. Nearly all organisations visited had identified a senior manager to act as a focal point for overseeing external communications with relevant organisations and individuals. The approach...with combined healthcare and social service organisations, provides a significantly improved opportunity for interface between professionals engaged in clinical or social care input.”

Issue 9 – Supervision of Junior Staff – Rating: 6

“In general, with regard to most non-clinical junior staff, there are effective systems in place for supervising their activities. However, consultants found few examples of formal, written procedures for ensuring that clinical staff have ready access to advice and support from their seniors. This does not imply that such processes are not in place, but these do need to be made more explicit. This is a particularly vulnerable arena in the context of clinical risk and needs more focused attention.”

Issue 10 – Assessing Competence – Rating: 6

“This is an area which HPSS organisations are taking increasingly seriously and many areas are being addressed and reviewed. In addition, all organisations appear to have effective arrangements for individual performance review for staff. However, the consultants are concerned in particular about issues (dealing with procedures to verify the qualifications, references, police checks, health status and competence of all locum and agency staff to fulfil the duties required by the HPSS organisation, and the procedure for informing all staff of their responsibility to limit their actions to those for which they are competent), where they saw very limited evidence that the appropriate methodologies and procedures had been formulated. These are matters which need to be addressed urgently, as they can have a major impact on enhancing the risks to patients/clients in particular, but also to the organisation generally.”

Issue 11 – Health and Safety and Related Issues – Rating: 8

“The consultants found examples of good work having been undertaken in all organisations regarding Health and Safety and related issues. Indeed, it is from these foundations that many of the risk management programmes have been built. The only point of concern with this issue is the possibility that some organisations may lose sight of the need to be continually vigilant in meeting on-going statutory and legislative requirements in this arena. Organisations cannot afford to become complacent in their pursuit of the wider challenging agenda, and should build on and maintain their current successes with Health and Safety and related issues.”

Issue 12 – Claims Management – Rating: 6

“The consultants found few examples of a claims management policy in accordance with the detailed and helpful framework set out in (the Department’s circular). It is likely that, because of the generally under-developed claims management function in most organisations, there is an excessive reliance on solicitors to manage claims of negligence. This incurs many costs which could be avoided if claims managers were given suitable training and more status within their organisation to genuinely manage the claims and the solicitors too. It is also important to note that, because of the central funding mechanisms for claims, there appears to be little financial or other incentive for HPSS organisations to pay more attention to this function.”